REMARKS

Entry of the foregoing, reexamination and reconsideration of the above-identified application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Status

As is correctly reflected in the Office Action Summary, Claims 1-13 are pending. Claims 1-13 stand rejected. Acknowledgement has been made to a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f) and copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau.

Summary of Amendments

By the foregoing amendments, the Specification has been amended to include an Abstract, as requested by the Examiner.

Also by the foregoing amendments, Applicants have amended Claims 1-13 to remove multiple dependencies; to correct minor and/or grammatical inconsistencies; and to remove "preferably . . . " language. The correction of the typographical error in Claim 13 is supported by, *inter alia*, Page 3, Lines 31 to 36 of the Specification. New Claims 14-20 result from such amendments and, therefore, derive support from at least Claims 1-13 prior to amendment. Accordingly, no new matter has been added.

Also by the foregoing amendments, Applicants have amended Claims 5 and 9 (and added claim 19) to delete the formerly-recited trade names and to add the

corresponding chemical description, as requested by the Examiner. No new matter has been added.

Rejection Under 35 U.S.C. § 112, Second Paragraph – Indefiniteness

Claims 3-6 and 8-10 were rejected under 35 U.S.C. § 112, Second Paragraph, as purportedly indefinite. *See Office Action mailed January 12, 2004, Pages 2-4.* This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Applicants have amended Claims 1-13 to delete material rejected by the Examiner, including ranges, the phrase "for instance," and trade names. New Claims 14-20 are free of such material.

From the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, Second Paragraph, indefiniteness rejection of Claims 1-13.

Minor Claim Informalities

Claims 5-12 were noted as reciting the expression "claimed in one of the preceding claims." *See Office Action mailed January 12, 2004, Page 4.* By the foregoing amendments, this expression has been deleted from the Claims. Accordingly, Applicants believe this informality issue has been rendered moot.

Rejection Under 35 U.S.C. § 103(a) – Stamm and/or DeBoeck

Claims 1-13 were rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over U.S. Patent No. 6,074,670 to Stamm *et al.* ("Stamm") or U.S.

Patent No. 5,545,628 to Deboeck *et al.* ("Deboeck") in view of Stamm. *See Office Action mailed January 12, 2004, Pages 4-6.* This rejection is respectfully traversed.

When applying 35 U.S.C. § 103, four tenets of patent law must be adhered to: (1) the claimed invention must be considered as a whole, (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination, (3) the references must be viewed without the benefit of impermissible hindsight vision, and (4) a reasonable expectation of success is the standard with which obviousness is determined. *See MPEP § 2141*, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986). To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See MPEP § 2142.*

Moreover, mere identification of each claimed element in the prior art is not sufficient to negate patentability. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Instead, there "must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the filed of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 536 (Fed. Cir. 1998). Otherwise, sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. *Rouffet*, 149 F.3d at 1357.

Applicants maintain that a *prima facie* case of obviousness has not been made out and that the Examiner has merely identified elements of Applicants' invention in the cited publications.

Stamm

Applicants respectfully assert that Stamm does not contain or suggest all of the claimed limitations.

Stamm pertains to a pharmaceutical composition containing micronized fenofibrate, a surfactant, and a hydrophilic polymer having increased solubility, thereby allowing increase bioavailability. *See Stamm, Abstract.* Stamm specifies that in such compositions, the fenofibrate represents from 5 to 50% by weight, and preferably from 20 to 45% by weight, relative to the weight of the composition. *See, e.g., Stamm Column 4, Line 66 to Column 5, Line 7.*

Contrarily, the compositions of Claims 1-20 require fenofibrate contents greater than or equal to 60% by weight, relative to the weight of the composition. Therefore, Stamm does not teach all limitations of Claims 1-20 and may not be used on its own to establish a *prima facie* case of obviousness.

Turning now to the second criteria for establishing prima facie obviousness, one would not expect to arrive at Applicants' easily-administered fenofibrate compositions based on the content of Stamm. Specifically, Stamm indicates that the hydrophilic polymer (any substance with a high molecular weight) has an affinity for water sufficient to allow dissolution and formation of a gel, such as polyvinylpyrrolidone (PVP), poly(vinyl alcohol), hydroxypropylcellulose,

hydroxymethylcellulose, hydroxypropylmethyl-cellulose (HPMC), gelatin, etc.; the preferred hydrophilic polymer being PVP. *See Stamm, Column 4, Lines 14-26.* Example 1 of Stamm prepares granules containing 31.6% PVP and 31.6% micronized fenofibrate (100 ÷ (100 + 100 + 114.3 + 2.0)) that results in tablets containing but 17.7% micronized fenofibrate (100 ÷ (100 + 100 + 114.3 + 2.0 + 92.7 + 145.7 + 5.8 + 3.3)). *See Stamm, Column 7, Lines 40-50.* Therefore, two tablets according to Example 1 of Stamm would be required to deliver 200 mg of fenofibrate (such as in Lipanthyl® 200M).

Applicants' invention, comprising greater than or equal to 60% micronized fenofibrate (recall, Stamm establishes a fenofibrate maximum of 50%), a surfactant , and a binding cellulose derivative, overcomes the inefficiency of Stamm by involving a low proportion of binder and, therefore, a formulation of a smaller size. *See, e.g., Specification Page 3, Lines 9-16.* Moreover, Applicants' invention even provides bioavailability at least equal to that of Lipanthyl® 200M. *See Examples 1-2.* Prior to Applicants' invention, one reading Stamm would not have expected to succeed in arriving at such a composition, especially in light of the 50% fenofibrate maximum established by Stamm.

In light of the foregoing, Applicants assert that a *prima facie* case of obviousness over Stamm has not been established.

Deboeck

Applicants respectfully assert that there is no suggestion or motivation to both combine and modify the teachings of Stamm and Deboeck.

First, unlike Stamm, Deboeck permits a range of fenofibrate from 5 to 95%, and prefers a range from 45 to 55%. *Deboeck, Column 3, Lines 49-62*. Second, unlike both Applicants' and Stamm's compositions, the compositions of Deboeck do not contain *micronized* fenofibrate. Third, Deboeck indicates a molten solution of non-micronized fenofibrate-polyglycolized glycerides which is subsequently allowed to cool. Deboeck adds a cellulose derivative into the molten suspension as a stabilizer which avoids the formation of fenofibrate crystals during cooling. *See Deboeck, Column 2, Lines 43-54*. Stamm, however, incorporates micronized fenofibrate into an aqueous or organic solvent.

Given the contrasting natures of Stamm and Deboeck with respect to at least these three components, Applicants maintain that one would not have been motivated to combine these two publications.

Regarding modification of Stamm and Deboeck, Applicants maintain that not only do these publications fail to motivate one to arrive at Applicants' invention, they actually teach away from doing so. As described above, Stamm sets forth a limit of 50% micronized fenofibrate and Deboeck prefers no more than 55%, whereas Applicants use at least 60%.

With respect to the cellulose derivative, contrary to Stamm and Deboeck, Applicants' invention uses the cellulose derivative, such as HPMC, as a solubilization adjuvant (as set forth in Claim 1). While preparing Applicants' formulation, this polymer is intimately mixed with the fenofibrate microparticles, allowed by the solubilization of the polymer in the suspension which contains the microparticles of fenofibrate and the surfactant. It is performed by the recrystallization of the

molecules of the polymer onto the surface of the particle of the active principle during drying, forming a layer of hydrophilic molecules onto the surface of the insoluble particles of the active principle, thereby making them soluble (or more soluble), and increasing the bioavailability of fenofibrate. Therefore, increase in contact between the active principle and polymer results in increase of bioavailability. Prior to Applicants' invention, one would have promoted such contact by simply increasing the proportion of polymer relative to fenofibrate, seeking to reach saturation.

From the foregoing, Applicants maintain that a *prima facie* case of obviousness has not bee made out. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of Claims 1-13 over Stamm or Stamm in view of Deboeck.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 838-6526 so that prosecution of the application may be expedited.

Respectfully submitted,
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